



Patent  
Case No.: 58625US002

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

First Named Inventor: ROSCOE, STEPHEN B.  
Application No.: 10/669390 Group Art Unit: Unknown  
Filed: September 24, 2003 Examiner: Unknown  
Title: METHOD OF FORMULATING A PHARMACEUTICAL COMPOSITION

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**CERTIFICATE OF MAILING**  
I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on  
December 30, 2003  
Date  
Signed by: Angie Zontelli

Dear Sir:

Pursuant to 37 CFR §§ 1.56, 1.97, and 1.98, enclosed is a completed Form PTO-1449, citing references submitted for consideration by the Examiner. Copies of any cited foreign patents, non-patent literature, and unpublished US application documents are enclosed. It is respectfully requested that the Examiner initial and return the enclosed Form PTO-1449 to indicate that each reference has been considered. A separate IDS listing US patent references has been submitted under EFS ID 52954.

It is believed that no fee is due; however, in the event a fee is required, please charge the fee to Deposit Account No. 13-3723.

Respectfully submitted,

Dec. 30, 2003  
Date

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Filing Date

September 24, 2003

First Named Inventor

Roscoe, Stephen B.

Art Unit

Unknown

Examiner Name

Unknown

Attorney Case Number

58625US002

Use as many sheets as necessary)

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## U.S. Patent Documents

Exam. Init.*	Cite No.	Document Number	Publication Date or Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Doc. Number-(Kind Code if Known)			
	A1	US-			
	A2	US-			
	A3	US-			
	A4	US-			
	A5	US-			
	A6	US-			

## Foreign Patent Documents

Exam. Init.*	Cite No.	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation (Check if yes)
		Ctry. Code	Number-KindCode (If known)				
	B1	WO	02/16941 A2	02-28-2002	Mitragotri et al.		

## OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Exam. Init.*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	C1	ASTM E-1147-92, "Partition Coefficient (N-Octanol/Water) Estimation by Liquid Chromatography", pp. 374-377, (2003).
	C2	Veber et al., "Molecular Properties That Influence the Oral Bioavailability of Drug Candidates", J. Med. Chem. vol. 45, pp. 2615-2623 (2002).
	C3	Lipinski et al., "Experimental and Computational Approaches to Estimate Solubility and Permeability in Drug Discovery and Development Settings", Advanced Drug Delivery Reviews, vol. 23 pp. 3-25 (1997).
	C4	Houk et al., "Membrane Models for Skin Penetration Studies", Chemical Reviews, vol. 88(3), pp. 455-471 (1988).
	C5	Hatanaka et al., "Prediction of Skin Permeability of Drugs. II. Development of Composite Membrane as a Skin Alternative", International Journal of Pharmaceutics, vol. 79, pp. 21-28 (1992).
	C6	Yaws, "Chemical Properties Handbook", New York, McGraw Hill, pp. 364-369 (1999).
	C7	J.G. Narin, "Remington's Pharmaceutical Sciences", 17 <sup>th</sup> edition, A.F. Gennaro ed., Mack Publishing Company, Easton, Pennsylvania, pp. 1492-1517 (1985).
	C8	Twist et al., "A Model for Alcohol-Enhanced Permeation Through Polydimethylsiloxane Membranes", Journal of Pharmaceutical Sciences, vol. 79, No. 1, pp. 28-31 (1990).

\*Examiner:

Date Considered:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO (modified)

Application Number

**10/669390**

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**RELATED U.S. APPLICATIONS - DO NOT PRINT**[illegible]

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